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October 2, 2017

via Federal Express

ATTN: Alan N. Drumheller
ARCOS Unit Chief
DEA Headquarters
8701 Morrissette Drive
Springfield, VA 22152

Re: *Touhy* request for ARCOS/DADS database production

Dear Mr. Drumheller:

On August 10, 2017, President Donald J. Trump "instructed his Administration to use all appropriate emergency and other authorities to respond to the crisis caused by the opioid epidemic." *See* Statement and Releases, The White House, Office of the Press Secretary (August 10, 2017). My law firm, along with the undersigned counsel below, are part of a consortium of law firms representing southern Ohio governmental entities (hereinafter, the "Ohio Plaintiffs")[1] in litigation against certain DEA registrants, which is pending in the United States District Court for the Southern District of Ohio, the Honorable Chief Judge Edmund A. Sargus, Jr. presiding. The Ohio Plaintiffs' lawsuits allege, among other things, that certain DEA registrants unlawfully failed to report suspicious orders of prescription opioids, resulting in the diversion of controlled substances into the illicit market. *See* 21 U.S.C.A. § 823; 21 CFR 1301.74; ORC

[1] Pending before the Honorable Edmund Sargus in the United States District Court of the Southern District of Ohio, Columbus Division, are the following cases: *Clermont County Board of County Commissioners v. AmerisourceBergen Drug Corporation, et al.* (2:17-cv-662); *Belmont County Board of Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-663); *Brown County Board of Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-664); *Vinton County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-665); *Jackson County Board of Commissioners v. AmerisourceBergen Drug Corporation, et al.* (2:17-cv-680); *Scioto County Board of Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-682); *Pike County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-696); *Ross County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-704); *City of Cincinnati v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-713); *City of Portsmouth v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-723); *Gallia County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-768); *Hocking County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-769); and *Lawrence County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-770).

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§ 4729.01(F); OAC §§ 4729-9-12, 4729-9-16, 4729-9-28; *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

A case management conference was held in the Ohio litigation before Chief Judge Sargus on September 26, 2017. The Ohio Plaintiffs requested leave to engage in early discovery and issue a *subpoena duces tecum* upon the DEA to produce the ARCOS/DADS database. Chief Judge Sargus suggested that we first contact you, make a formal *Touhy* request, and then report back at the next conference, which is scheduled for **October 24, 2017**.[2] This letter is our attempt to fully and completely comply with the Court's directive.

All manufacturers and distributors of prescription opiates are required by federal law to report each transaction to a national database -- the ARCOS/DADS database. This database can be used, along with other information, to identify unlawful sales of prescription opiates to every pill mill in America. However, the data has been concealed behind a curtain of "trade secret" until recently, when a Pulitzer Prize winning journalist gained access to the data in West Virginia. The public disclosure of the West Virginia data initiated a Congressional investigation.

On behalf of the citizens of southern Ohio, and consistent with President Trump's directive, the Ohio Plaintiffs hereby request that the United States Department of Justice (DOJ) and the Drug Enforcement Administration (DEA),[3] agree to produce the ***Automated Records and Consolidated Orders System/Diversion Analysis and Detection System*** (ARCOS/DADS) (69 FR 51104-02) to bring transparency and accountability concerning the unconscionable volume of prescription opiates distributed to our clients' communities. We are seeking production of electronically stored information contained within the ARCOS/DADS database, in its native format related to the sale of controlled substances, including hydrocodone and oxycodone, in the United States from January 1, 1995 to the present. We ask that you produce the data on or before October 17, 2017.

We believe this request is consistent with the *Touhy* regulations adopted by the Justice Department, 28 C.F.R. § 16.21 *et seq.* as well as Rule 45[4] of the Federal Rules of Civil Procedure (which would govern the issuance of a subpoena). Consistent with §§ 16.24(c) and Local

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[2] We ask for your appearance at the status conference and will forward a copy of the Notice once it is entered by the Court.

[3] The system location is set forth in the federal regulations. *See* 21 CFR § 1321.01, DEA Mailing Addresses, United States Department of Justice, Drug Enforcement Administration, Pharmaceutical Investigations Section, Reports to ARCOS.

[4] See *In re Packaged Ice Antitrust Litig.*, 2011 WL 1790189 (E.D. Mich. May 10, 2011) (concluding that the Sixth Circuit would join the opinions of those courts, mostly in this century, that have concluded that Federal Rule of Civil Procedure 45 and various available privilege rules provide sufficient limitations on discovery to adequately address legitimate governmental interests in objecting to a motion to compel compliance with a valid federal court subpoena).

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Rule 37.1, we are willing and able to discuss the scope of this request as well as the most efficient means to transfer and/or gain access to the data at your earliest convenience.

The DOJ *Touhy* regulations set forth procedures to be followed with respect to the production or disclosure of the ARCOS/DADS database in all federal and state proceedings in which the United States is not a party when a subpoena, order, or other demand (hereinafter collectively referred to as a "demand") of a court or other authority is issued for such material or information. 28 C.F.R. § 16.21(a)(2). We anticipate that certain DEA registrants may be hesitant to consent to the disclosure of data. Indeed, this data may be used to establish their violations of federal law and civil liability to our governmental entity clients. For the reasons discussed below, there is no valid basis to withhold this information from public disclosure and we contend that it be made public.

28 C.F.R. § 16.22 governs production or disclosure of documents by the DEA in a federal proceeding in which the United States is not a party.

28 C.F.R. § 16.22(a) states that the DEA may not produce or disclose any information in response to a *Touhy* demand without prior approval of the proper Department official in accordance with §§ 16.24 and 16.25. We are aware that state-wide ***aggregate*** data from the ARCOS/DADS database is available online.[5] However, this data is insufficient to meet our needs. We are also aware that traditionally, the DEA refuses to disclose data related to conduct by individual DEA registrants. *Madel v. US Dep. of Justice*, 784 F.3d 448 (8th Cir. 2015). In short, we are not aware of any "prior approval" by the DOJ and/or DEA to release the data sought in this demand, and we believe this *Touhy* letter presents an issue of first impression.

28 C.F.R. § 16.22(b) states that whenever a *Touhy* demand is made, the DEA shall immediately notify the U.S. Attorney for the district where the issuing authority is located. The U.S. Attorney for the Southern District of Ohio is:

The Honorable Benjamin C. Glassman
U.S. Attorney's Office
303 Marconi Boulevard, Suite 200
Columbus, OH 43215
(phone: 614-469-5715)
(fax: 614-469-5653)

A courtesy copy of this letter and proposed subpoena has been forwarded to Mr. Glassman.

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[5] https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

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28 C.F.R. § 16.22(d) states that when information other than oral testimony is sought by a demand, the responsible U.S. Attorney shall request a summary of the information sought and its relevance to the proceeding. The following summary is intended to satisfy this provision.

These civil actions are brought by city and county governments in southern Ohio against those in the chain of distribution, including manufacturers and distributors, who are responsible for the illegal diversion of prescription opiates into the illicit market, thereby creating a serious public health and safety crisis throughout southern Ohio. The Ohio Plaintiffs allege that certain DEA registrants failed to comply with their duties to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating throughout southern Ohio and the United States. The Ohio Plaintiffs further allege that as a result of these registrants' failure to comply with their lawful duties to prevent diversion, the Ohio Plaintiffs suffered damage in the form of (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; (5) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, among other things.

The ARCOS/DADS[6] system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 826(d)) and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971. 69 FR 51104-02.

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables

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[6] "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.) by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, https://www.deadiversion.usdoj.gov/arcos/#background (last visited September 7, 2017)

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the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level. *See* ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to ultimate consumers. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, receipts, purchase orders, and prescriptions, and include the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances. Information can be retrieved from this system of records by use of various data elements such as name, address, DEA registrant number, name of business, or social security number. 69 FR 51104-02.

All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is located at Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

All DEA registrants must "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). The complete dataset contained in the ARCOS/DADS system is ***relevant*** and necessary because, among other things, it will reveal:

a. The size of orders nationally, regionally, and locally, as a baseline to determine orders which, on their face, are of an unusual size;

b. The pattern of orders nationally, regionally, and locally, as a baseline to determine orders that, on their face, deviate substantially from a normal pattern; and

c. The frequency of orders nationally, regionally, and locally, as a baseline to determine orders, which on their face, are of unusual frequency.

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The Ohio Plaintiffs specifically seek disclosure of ARCOS/DADS data related to the sale of controlled substances, namely hydrocodone and oxycodone, dating back to **January 1, 1995**. This timeframe coincides with the introduction of OxyContin©[7] into the United States marketplace and the subsequent evolution of the opiate epidemic declared by the President of the United States. *See* Barack Obama, President of the United States, Proclamation 9499, *Prescription Opioid and Heroin Epidemic Awareness Week*, 2016, 81 FR 65173 (September 16, 2016). Recently, President Donald J. Trump "instructed his Administration to use all appropriate emergency and other authorities to respond to the crisis caused by the opioid epidemic." *See* Statement and Releases, The White House, Office of the Press Secretary (August 10, 2017).

The ARCOS/DADS system uniquely has access to ***all*** of the data submitted by each DEA registrant from the across the country.[8] These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, and other analyses.[9]

The Ohio Plaintiffs respectfully submit that this data contains evidence which will definitively establish a national, regional, and local baseline for DEA registrant conduct as well as reveal specific conduct by the defendants within the southern Ohio communities. Both facts are discoverable and reasonably calculated to lead to the discovery of admissible evidence. Similar evidence was produced related to a like investigation in the State of West Virginia[10] and has been requested by the United States House of Representatives Committee on Energy and Commerce.[11] The Ohio Plaintiffs are seeking similar access to data nationally, regionally and locally.

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[7]OxyContin is a prescription narcotic pain reliever that was approved by FDA in **1995**. It is manufactured by Purdue Pharma LP, and its active ingredient is oxycodone, a derivative of opium. https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm207196.htm.

[8] The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

[9] https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

[10] Eric Eyre of *Charleston Gazette-Mail*, Charleston, WV, The 2017 Pulitzer Prize Winner in Investigative Reporting, available at http://www.pulitzer.org/winners/eric-eyre (last visited July 3, 2017); Eric Eyre, Drug firms poured 780M painkillers into WV amid rise of overdoses, Charleston Gazette-Mail, December 17, 2016, available at http://www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses (last visited July 3, 2017); Subcommittee on Oversight and Investigations of the United States House of Representatives Energy and Commerce Committee outlined in the *Letters to Distributors and the DEA Regarding Alleged Pill Dumping in West Virginia* dated May 9, 2017 (available online).

[11] *See* https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170508DEA.pdf.

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The Ohio Plaintiffs are willing and able to bear the expense of transferring the data from the ARCOS system to a platform which will enable access, transparency and accountability. We are seeking the production of the ARCOS database in its native format[12] which will include all fields of information as commonly stored. Understanding that this request may include a significant amount of data, please provide the size of the requested information and we will provide the appropriate external storage device to support the instant request. In addition to the native format of the requested information, we are also requesting production of all Excel spreadsheets and/or other searchable formats of the data to permit identification of information including (1) Each Seller's name, address, and DEA number; (2) Each Buyer's name, address, and DEA number; (3) Date of each transaction; (4) Type of each transaction (sale/return); (5) Drug name and NDC number for each transaction and (6) Quantity of pills sold. We are aware, on information and belief, that such summaries exist and are readily available to disclose.

28 C.F.R. § 16.26 provides considerations in determining whether production or disclosure should be made pursuant to a demand.

28 C.F.R. § 16.26(a) provides that when deciding whether to make disclosures pursuant to a demand, Department officials and attorneys should consider: (1) Whether such disclosure is appropriate under the rules of procedure governing the case or matter in which the demand arose, and (2) Whether disclosure is appropriate under the relevant substantive law concerning privilege.

28 C.F.R. § 16.26(a)(1). The Ohio Plaintiffs appeared before the Honorable Chief Judge Edmund Sargus, with all parties present, on September 26, 2017, and discussed the Ohio Plaintiffs' request to issue an early *subpoena duces tecum*[13] upon the DEA for production of the database

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[12] As to the ARCOS database please provide details related to:

- Database product name, version, latest service pack (i.e. Microsoft SQL Server 2012 SP3)
- Operating system required to run the database (i.e. Windows Server 2012)
- Any account username and password with appropriate permissions to
  - observe all database meta data (such as lists of tables, views and stored procedures)
  - query all relevant tables
- Any tools required to query the database
- Any relevant meta data required to understand
  - Where relevant data is stored (table and field names)
  - How tables are related
  - Any special information required to interpret the contents of relevant fields

[13] Rule 45 permits the Ohio Plaintiffs to invoke the Court's subpoena power to obtain non-privileged materials in the possession of the Department. *Fann v. Floied,* No. 4:03-CV-042, 2006 WL 849847, at *4 (E.D. Tenn. Mar. 28, 2006) ("A federal-court litigant, on the other hand, can seek to obtain the production of documents from a federal agency by means of a federal subpoena."); *In re Packaged Ice Antitrust Litig.*, No. 08-MD-01952, 2011 WL 1790189, at *2-*3 (E.D. Mich. May 10, 2011); *cf. In re Bankers Tr. Co.,* 61 F.3d 465, 471 (6th Cir. 1995) (refusing to enforce Fed.

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pursuant to Rule 45(a)(1)(D). In response, Chief Judge Sargus noted for the record that an amended complaint had recently been filed naming additional parties who had not yet appeared, a Rule 26(f) conference had yet to be conducted, and an MDL petition had recently been filed seeking conditional transfer of similar litigation nationwide to a single locale. Accordingly, Chief Judge Sargus deferred a decision on the merits of such a request, but encouraged the Ohio Plaintiffs to approach you and/or the United States Attorney and begin discussions regarding the *Touhy* regulations.

As such, this demand is made in the form of this letter in lieu of service of the proposed *subpoena duces tecum*. Please advise if you wish us to proceed otherwise.

28 C.F.R. § 16.26(a)(2). The Ohio Plaintiffs are unaware of any "privilege" which attaches to the ARCOS/DADS database and/or its summary reports generated therefrom.

28 C.F.R. § 16.26(b) sets forth six factors the Department must consider when responding to a demand. Each factor is addressed in turn:

> **28 C.F.R. § 16.26(b)(1)** Disclosure would violate a statute, such as the income tax laws, 26 U.S.C. 6103 and 7213, or a rule of procedure, such as the grand jury secrecy rule, F.R.Cr.P., Rule 6(e). The Ohio Plaintiffs submit this factor is not applicable;
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> **28 C.F.R. § 16.26(b)(2)** Disclosure would violate a specific regulation. The Ohio Plaintiffs submit this factor is not applicable;
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> **28 C.F.R. § 16.26(b)(3)** Disclosure would reveal classified information, unless appropriately declassified by the originating agency. The Ohio Plaintiffs note that the database is designated in the Federal Register as "not classified." 69 FR 51104-02.
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> **28 C.F.R. § 16.26(b)(4)** Disclosure would reveal a confidential source or informant, unless the investigative agency and the source or informant have no objection. The Ohio Plaintiffs submit this factor is not applicable;
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> **28 C.F.R. § 16.26(b)(5)** Disclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which

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Reserve regulation purportedly prohibiting bank as party in litigation from complying with discovery order issued by the United States District Court for the Southern District of Ohio); *U.S. ex rel. Roby v. Boeing Co.*, 189 F.R.D. 512, 517 (S.D. Ohio 1999) (same).

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would thereby be impaired. The Ohio Plaintiffs submit this factor is not applicable. Indeed, the Ohio Plaintiffs are governmental entities who are seeking to enforce their rights under the law;

28 C.F.R. § 16.26(b)(6) Disclosure would improperly reveal trade secrets without the owner's consent. The Ohio Plaintiffs submit this factor is not applicable. As alleged in the Ohio Plaintiffs' amended pleadings, through information exchanged up the chain of distribution through "kickback" programs, IMS data, and "know your customer" information, the DEA registrants are already aware of the conduct of their competitors. Moreover, unlawful activities are, by definition, not subject to trade secret protections. See also, *Madel v. United States*, No. CV 13-2832 (PAM/FLN), Document 127, available on PACER (D. Minn. Aug. 30, 2017) (holding that historical data in the ARCOS database does not qualify for trade-secret protection).

The decision and record in *Madel v. US Dep. of Justice*, 784 F.3d 448 (8th Cir. 2015) fully sets forth the position of the various interested parties related to this factor. In *Madel*, an American citizen properly served a FOIA request upon the DEA to disclose oxycodone transactions in the state of Georgia by Cardinal Health, Inc., AmerisourceBergen Corp. and McKesson Corp. (all three are named defendants in the Ohio litigation) set forth in the ARCOS database. The DEA refused the FOIA request, citing a statutory FOIA exemption,[14] claiming disclosure would result in "competitive harm" and "likely to cause substantial harm to the competitive position of the person from whom the information was obtained.[15] *Id.* at 452. Each the DEA registrants also objected to the disclosure. *Id.* at 453.[16] The district court granted summary judgment in favor of the DEA, finding the withheld documents exempt under 5 U.S.C.A. § 552(b)(4).

On appeal, the Eighth Circuit Court of Appeals reversed the district court for failure to make an express finding on segregability. Notably, the *Madel* Court commented:

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[14] The FOIA statute expressly excludes from disclosure matters that are "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C.A. § 552(b)(4).

[15] In support of its position, the DEA submitted the Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA" and the "release of the information would result in substantial competitive harm to [Cardinal Health, AmerisourceBergen and McKesson Corp.")

[16] *See also* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

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> Although DEA expresses the concern that any connection between individual buyers and sellers would lead to substantial competitive harm, this is not supported by the Declaration. The Declaration does not address how disclosure of the data from, say, 2007, leads to the proffered substantial competitive harms of a competitor "target[ing] specific markets" or "forecast[ing] potential business of new locations." The claims of harm are undermined by DEA's public release of four charts showing total dosage units sold per month by Cardinal Health to four named buyers in Florida over four years. The Declaration also does not address whether disclosing only distributions over 100,000 or 200,000 units per year, as Madel offered, would have the same competitive harm as disclosing all the data. The case is remanded to the district court for an express finding on segregability.

Madel v. U.S. Dep't of Justice, 784 F.3d 448, 454 (8th Cir. 2015). The case was remanded back to the United States District Court for the District of Minnesota for further action.

As you know, the federal court in Minnesota has since rejected the DEA's position on protecting Cardinal Health, AmerisourceBergen and McKesson. On January 11, 2017, United States District Court Judge Paul Magnuson entered a Memorandum and Order holding "company-specific information by the buyer's county, business activity, drug type, transaction date, dosage units, and total grams for the years Madel requests is not exempt from disclosure under (b)(4)." *Madel v. United States*, No. CV 13-2832 (PAM/FLN), 2017 WL 111302, at *4 (D. Minn. Jan. 11, 2017). The federal court bluntly concluded:

> The Court has given [the DEA] the benefit of the doubt throughout this litigation, and [the DEA] have time and again failed to establish that they deserve that benefit. Whether by refusing to negotiate with Madel in good faith, or by publicly releasing data that they had mere months before insisted was too sensitive to ever make public, [the DEA] have lost their credibility with this Court. The Eighth Circuit was clear: it is [the DEA]'s burden to show that information responsive to Madel's requests is not reasonably segregable from information not subject to disclosure. Broad pronouncements and general explanations will not suffice to meet this burden, and [the DEA] have offered nothing more than that here. [The DEA] have failed to establish that there is no non-exempt information responsive to Madel's requests that is not segregable from exempt information.

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Madel v. United States, at *3. The order casts doubt upon the entire scope of the FOIA exemption claimed by the DEA and concludes by urging the parties "to negotiate the release of information from the company-specific reports." *Id.* at *4.

Nearly nine months later, the parties sought clarification from the Court on the meaning of its prior ruling and the DEA invoked, for the first time, the Trade Secrets Act and refused to disclose the supplier companies' names. The federal court entered a more blunt ruling:

> The information Madel requests is now more than five years old. (See id. at 5 (noting that the information is "at least five years, and up to 11 years, old").) It is no longer a trade secret, if it ever was. Nor is it protected from disclosure under any exemption to the FOIA. Madel is correct: the non-exempt information in the spreadsheets includes the name of the supplier companies as well as the other information identified in the Court's previous Order.
>
> The Court expects the Government to release this information immediately. Madel brought this lawsuit in October 2013 and it is time to bring it to a close. The Court will not look favorably on any additional attempts to delay disclosure or to seek further advice from the Court on the issues that have been clearly and finally resolved.

Madel v. United States, No. CV 13-2832 (PAM/FLN), Document 127, available on PACER (D. Minn. Aug. 30, 2017). As of the date of this letter, no further docket entry has been entered.

The Ohio Plaintiffs pick up where Mr. Madel left off. Of note, FOIA requests are different and distinct from *Touhy* requests and both are governed by two separate standards, regulations and procedures. *Benhoff v. United States Dep't of Justice*, No. CV16-1095-GPC(JLB), 2016 WL 6962859, at *3 (S.D. Cal. Nov. 29, 2016). "In federal court, the federal government has waived its sovereign immunity, *see* 5 U.S.C. § 702, and neither the Federal Housekeeping Statute nor the *Touhy* decision authorizes a federal agency to withhold documents from a federal court. *Exxon Shipping [Co. v. United States Dep't of Interior,* 34 F.3d 774, 777-78 (9th Cir. 1994)]". *Fann v. Floied, supra; Roby,* 189 F.R.D. at 517 (S.D. Ohio 1999) (*Touhy* regulations cannot override the rules of civil procedure in a civil case citing 6th Circuit's opinion in *In re Bankers Tr. Co., supra*).

The central and only issue in this case is whether "disclosure would improperly reveal trade secrets without the owner's consent." 28 C.F.R. § 16.26(b)(6).

With regard to consent, the owner of the data is presumably the reporting DEA registrants. Three of the DEA registrants appeared before Chief Judge Sargus and offered no objection to the

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issuance of this *Touhy* letter. Of course, each can speak for themselves and may be reached through counsel of record from the hearing:

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There are about 1100 Distributors and Manufacturers that report to ARCOS. These 1100 are just a small part of the over 1,000,000 registrants in Drug Enforcement Administration's (DEA) Controlled Substances Act (CSA) database. 30,000,000+ transactions are reported each year.[17] Obtaining consent from all DEA registrants is not practicable.

Moreover, consent is not required under (b)(6) if the "Deputy or Associate Attorney General determines that the administration of justice requires disclosure." **28 C.F.R. § 16.26(c)**. Nor is consent required if there is no objection by the originating component, the demand is deemed appropriate and a determination is made that disclosure will not reveal trade secrets. **28 C.F.R. § 16.24(b)**.

With regard to the merits of (b)(6), the Ohio Plaintiffs respectfully submit that the requested data is not a "trade secret." Courts of Appeals have embraced varying versions of a "convoluted test" that rests on judicial speculation about whether disclosure will cause competitive harm to the entity from which the information was obtained. *New Hampshire Right to Life v. Dep't of Health*

[17] https://www.deadiversion.usdoj.gov/arcos/faq.htm#howmanyreport

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& Human Servs., 136 S. Ct. 383, 384, 193 L. Ed. 2d 412 (2015). The *National Parks* test has received widespread acceptance which involves a two-part test:

> [C]ommercial or financial matter is "confidential" ... if disclosure of the information is likely ... either ... (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.

Critical Mass Energy Project v. Nuclear Regulatory Comm'n, 975 F.2d 871, 873 (D.C. Cir. 1992) (en banc).

With regard to the first *National Parks* factor, disclosure of the ARCOS/DADS data will not impair the Government's ability to obtain information in the future. DEA registrants are required by federal law to report records of sales of controlled substances with ARCOS/DADS. 21 C.F.R. § 1304.33(c); 21 U.S.C. 827(d).

With regard to the *National Parks* second factor, the Ohio Plaintiffs respectfully submit that disclosure of the ARCOS/DADS data will ***not*** "cause substantial harm to the competitive position of the person from whom the information was obtained" for the following reasons:

1. The only courts (known to the undersigned) to address whether the ARCOS/DADS data is a "trade secret" are the district court and appellate court in the *Madel* case. The DOJ and DEA are litigants in the case and are fully aware of the precedent. The federal court has, as of the submission of this demand, rejected all arguments attempting to designate the data as a trade secret.

2. The data requested is historical and reaches back to January 1, 1995. To the extent the data may have been a trade secret, it is now obsolete. Obsolete information cannot form the basis for a trade secret claim because the information has no economic value. *Fox Sports Net N., L.L.C. v. Minnesota Twins P'ship*, 319 F.3d 329, 336 (8th Cir. 2003).

3. As outlined in the Declaration submitted by the DEA in the *Madel* case, the "substantial harm to competitive position" argument is premised upon a concern by the DEA registrants that disclosure of the data would be "use[d] to target specific markets, forecast potential business of new locations or to gain market share in existing locations." *See* Myrick Declaration, ¶39. In other words, Cardinal Health does not want competitors poaching its best pill mill customers. If preservation of the choice locales to sell opium pills is, in fact, a trade secret, then sharing of the data is only prejudicial if shared with the competition. The Ohio Plaintiffs propose the entry of a protective order for the preceding five (5) years (2012-2017) which prevents the public disclosure of the data without court approval and/or customer consent. The "harm"

proposed by the DOJ/DEA is inapplicable to the timeframe of 1995-2012 and should not be considered a trade secret.

Finally, consent is not needed nor is a trade secret a justification if disclosure is necessary to pursue a civil or criminal prosecution or affirmative relief, such as an injunction. 28 C.F.R. § 16.26(c). Each of the factors to be considered are addressed in turn:

16.26(c)(1). The seriousness of the violation or crime involved. The Ohio Plaintiffs allege the DEA registrants engaged in repeated, systemic unlawful conduct which resulted in the diversion of millions of prescription opiates. These violations have enabled and fueled the opioid epidemic which is plaguing southern Ohio communities, the State of Ohio and the United States of America. The violations of law can be objectively identified if proper resources are applied to examine the data in the ARCOS/DADS database. This matter indisputably is serious. Indeed, the defendants' conduct as pled in the Ohio Plaintiffs' complaints violates the Racketeer Influenced & Corrupt Organizations Act, 18 U.S.C §§ 1961-1968.

16.26(c)(2) The past history or criminal record of the violator or accused. The DEA registrants have repeatedly broken the law and been fined by the DEA. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[18] These actions include the following:

(a) On April 24, 2007, the DEA issued *an Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;

(b) On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

(c) On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida

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[18] *The Drug Enforcement Administration's Adjudication of Registrant Actions*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014).

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Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

(d) On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

(e) On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

(f) On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

(g) On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado;

(h) On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;

(i) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

(j) On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL,

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Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

Rather, than abide by their non-delegable duties under public safety statutes, the DEA registrants, individually and collectively through trade groups in the industry, pressured the U.S. Dept. of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[19]

The Ohio Plaintiffs are not so constrained nor answerable to Washington politicians. We intend to marshal the resources of the civil justice system to hold accountable those in the chain of distribution of prescription opiates that broke the law. We simply need access to the data in the sole possession of the DEA.

16.26(c)(3) The importance of the relief sought.

Our nation as a whole and the communities who are represented by the governmental Ohio Plaintiffs are in crisis as a result of the unlawful diversion of opioids. The litigation from which this request derives seeks to stem the tide of the crisis and put these communities back together.

16.26(c)(4) The importance of the legal issues presented.

As discussed above, this data is sought to hold the manufacturers and distributors, who failed to comply with their legal duty to prevent diversion, liable for the harm they caused in the Ohio Plaintiffs' communities. In addition to obtaining damages, the litigation will provide a deterrent effect and prevent further harm in the future.

Please note that Chief Judge Sargus has requested the parties appear before his Court on October 24, 2017, at 1:30 pm, to provide an update regarding the case status as well as the DEA's response to the *Touhy* letter. Thus, this demand respectfully requests disclosure of the ARCOS/DADS database on or before October 17, 2017. Otherwise, the Ohio Plaintiffs request

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[19] *See* Lenny Bernstein and Scott Higham, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control*, THE WASHINGTON POST (October 22, 2016); Lenny Bernstein and Scott Higham, *Investigation: U.S. senator calls for investigation of DEA enforcement slowdown amid opioid crisis*, THE WASHINGTON POST (March 6, 2017); Eric Eyre, *DEA agent: 'We had no leadership' in WV amid flood of pain pills*, Charleston Gazette (February 18, 2017).

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the DEA comply with **28 C.F.R. § 16.27**.[20] In other words, we request your appearance at the status conference.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 2, 2017

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[20] If response to a demand is required before the instructions from the appropriate Department official are received, the responsible official or other Department attorney designated for the purpose shall appear and furnish the court or other authority with a copy of the regulations contained in this subpart and inform the court or other authority that the demand has been or is being, as the case may be, referred for the prompt consideration of the appropriate Department official and shall respectfully request the court or authority to stay the demand pending receipt of the requested instructions. 28 C.F.R. § 16.27.

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cc:
Honorable Benjamin C. Glassman, U.S. Attorney's Office, Southern District of Ohio
(via hand delivery)

Re: *Touhy* request for ARCOS/DADS database production

cc: *continued*
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